

REMARKS

I. Claim Amendments

Claims 38-51 are pending. Without acquiescing in the rejections, without prejudice to pursue broader claims in a continuation application, and without disclaiming any subject matter, Applicants have canceled claims 27-30 and 32-37.

New claims 38-51 have been added. Support for these new claims is found in the specification and claims as originally filed.

II. Information Disclosure Statements

Applicants wish to have made of record Information Disclosure Statements ("IDS papers") filed in the present case. Applicants filed IDS papers on May 26, 1998, and on December 4, 1998, as acknowledged on the Notification of Acceptance of Application Under 35 U.S.C. 371 and 37 C.F.R. 1.494 or 1.495 mailed February 25, 1999.

However, Applicants have not received copies of the 1449 forms from the Examiner.

Applicants therefore respectfully request the Examiner to consider the submitted documents, and to provide Applicants with initialed copies of the 1449 forms to indicate her consideration of the submitted documents. If the Examiner needs a copy of any of the submitted documents, or of the IDS papers, the undersigned would be happy to provide them.

III. Rejection Under 35 U.S.C. § 103(a)

In the Office Action dated April 17, 2000, claims 27-30 and 32-37 are rejected as being allegedly unpatentable over Lohaus et al. (U.S. 4,797,409) and Dittmar et al. (U.S. 4,185,106). See Office Action at 2. The Office Action sets forth the position that Lohaus et al. and Dittmar et al. teach compositions comprising related 1-hydroxy-2-pyridones which render obvious Applicants' claims 27-30 and 32-37. Without acquiescing in the rejection, and without prejudice or disclaimer, Applicants have canceled composition claims 27-30 and 32-37. This rejection should therefore be withdrawn as moot.

IV. Patentability of New Claims 38-51

During previous prosecution, Applicants' composition claims 27-30 and 32-37 were amended to recite the intended use. However, the language "treatment for seborrheic dermatitis" was given no patentable weight in the composition claims. See Office Action at 4. To clarify issues and to keep the prosecution of composition claims separate, Applicants have submitted new claims drawn to methods of treating a human or animal patient in need of treatment for seborrheic dermatitis. These new claims are based loosely on claims 14-26 and 31, canceled without prejudice or disclaimer before the filing of this CPA. See Amendment filed September 21, 1999, at 1.

Applicants assert that claims 38-51, drawn to methods of treating a human or animal patient in need of treatment for seborrheic dermatitis, are patentable.

Seborrheic dermatitis is a disorder primarily of the scalp

which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites. . . . In severe cases, the scalp can have a secondary infection, and the changes can then exhibit a spongy consistency, vesicle and crust formation and can weep.

Specification at 1, lines 4-11. Moreover, people of all ages suffer from this disease, which afflicts 1-3% of the population. Seborrheic dermatitis is thought to be caused by yeast fungi of the strain *Pityrosporum*. *Id.* at lines 32-33. Heretofore, seborrheic dermatitis has been treated with either antiinflammatories such as corticosteroids, or, more recently, with antimycotics. *See id.* at 1, lines 26-28. Yet no treatment has been found that can relieve inflammation while killing off the infection. *See generally* the art of record in this case.

The claimed method of treating a human or animal patient in need of treatment for seborrheic dermatitis unexpectedly provides a novel, efficacious, and comprehensive treatment for the disease, because the treatment may result in both an antiinflammatory and antimycotic effect when applied to a patient suffering from seborrheic dermatitis. *See* specification at 1, lines 34-37.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to

one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

MPEP § 2142, *citing In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

None of the documents cited by the Examiner meet these criteria. Of particular note, Dittmar et al. teaches away from the present invention. In spite of disclosing 1-hydroxy-2-pyridones, Dittmar et al. reveals that disclosed compositions may "contain further additives [such as] . . . anti-seborrheic agents" Dittmar et al., at col. 6, lines 11 and 24. Taking this document as a whole, one skilled in the art would not foresee the presently claimed method of treating a human or animal patient in need of treatment for seborrheic dermatitis. Indeed, one skilled in the art would be taught away from such use by Dittmar et al.

Similarly, Lohaus et al. does not teach antiseborrheic activity, nor activity against any yeast associated with seborrheic dermatitis. Yoshimasa et al. (J. SCCJ, 22(3), 165-70, (1988); CAPlus abstract) teaches hinokitiol to be the better inhibitor of *P. ovale* than a 1-hydroxy-2-pyridone. Saint-Leger et al. (J. Soc. Cosmet. Chem., 40(2), 109-118, (1989); Biosis abstract) teaches a 1-hydroxy-2-pyridone, characterized as an antidandruff agent, as having an affect on *P. ovale*, yet does not overcome the preference established by Yoshimasa et al. Kamegai et al. (U.S. 5,753,600) teaches

salts of certain other 1-hydroxy-2-pyridones in detergent compositions in broad pH ranges, but does not suggest antimycotic properties of these salts. There exists no motivation to combine selected elements of these references, when each reference is considered as a whole. This is particularly true when these references are considered in light of the unexpected and surprising teachings of the present application. Nor is there a reasonable expectation of success found in that selective and unintuitive combination without the hindsight afforded by the present invention.

CONCLUSION

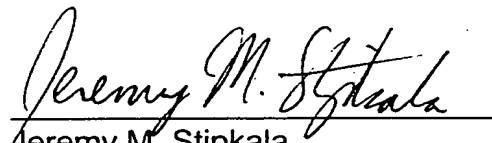
In light of the foregoing, Applicants respectfully request that the above Amendment be entered, and the claims as amended be reconsidered in light of the arguments set forth above.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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By:


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Dated: July 17, 2000

CPE/ARJ/JZS

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In re Application of: Manfred BOHN, et al.

Serial No.: 09/077,194

Filed: December 4, 1998

For: USE OF 1-HYDROXY-2-PYRIDONES FOR THE TREATMENT OF SEBORRHEIC
DERMATITIS

Group Art Unit: 1614

Examiner: V. Kim

1. AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.111

Dated: July 17, 2000

CASE REF: 2481.1596-00

(due date: 07/17/00)

ARJ:JMS/pap

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